

117TH CONGRESS
1ST SESSION

S. 1176

To establish a grant program to support the manufacture and stockpiling
of essential generic antibiotic drugs.

IN THE SENATE OF THE UNITED STATES

APRIL 15, 2021

Ms. SMITH (for herself and Mr. CASSIDY) introduced the following bill; which
was read twice and referred to the Committee on Health, Education,
Labor, and Pensions

A BILL

To establish a grant program to support the manufacture
and stockpiling of essential generic antibiotic drugs.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Onshoring Essential
5 Antibiotics Act”.

6 **SEC. 2. ESSENTIAL GENERIC ANTIBIOTIC PROGRAM.**

7 (a) GRANT PROGRAM.—

8 (1) ESTABLISHMENT.—Not later than 60 days
9 after the date of enactment of this Act, the Sec-
10 retary shall establish a program to provide grants to

1 manufacturers of essential generic antibiotic drugs,
2 or the active pharmaceutical ingredient or key start-
3 ing material of an essential generic antibiotic drug,
4 to support activities described in paragraph (3).

5 (2) ELIGIBLE ENTITIES.—The Secretary shall
6 award grants under this subsection to not more than
7 3 manufacturers of an essential generic antibiotic
8 drug. Each such recipient shall be a manufacturer
9 that—

10 (A) has implemented and maintains an ef-
11 fective quality management system, under parts
12 210 and 211 of title 21, Code of Federal Regu-
13 lations (or any successor regulations);

14 (B) has a strong record of compliance with
15 the requirements of the Federal Food, Drug,
16 and Cosmetic Act (21 U.S.C. 301 et seq.);

17 (C) uses complex pharmaceutical manufac-
18 turing to produce a finished drug product or ac-
19 tive pharmaceutical ingredient pursuant to an
20 application approved under section subsection
21 (c) or (j) of section 505 of the Federal Food,
22 Drug, and Cosmetic Act (21 U.S.C. 355);

23 (D) commits to using advanced manufac-
24 turing in its manufacturing operations; and

1 (E) has existing manufacturing facilities
 2 and operations in the United States.

3 (3) USE OF FUNDS.—A recipient of a grant
 4 under this subsection may use such grant funds to—

5 (A) with respect to manufacturing an es-
 6 sential generic antibiotic drug—

7 (i) expand, upgrade, or recommission
 8 an existing manufacturing facility located
 9 in the United States; or

10 (ii) construct a new manufacturing fa-
 11 cility in the United States; and

12 (B) manufacture essential generic anti-
 13 biotic drugs.

14 (b) USE OF FUNDS TO PURCHASE ESSENTIAL GE-
 15 NERIC ANTIBIOTIC DRUGS FOR STOCKPILING.—The Sec-
 16 retary may use amounts appropriated under this section
 17 to purchase, store, stockpile, or disposition essential ge-
 18 neric antibiotic drugs manufactured in the United States.

19 (c) DEFINITIONS.—For purposes of this section:

20 (1) ACTIVE PHARMACEUTICAL INGREDIENT.—

21 The term “active pharmaceutical ingredient” has the
 22 meaning given such term in section 744A of the
 23 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 24 379j–41).

1 (2) ESSENTIAL GENERIC ANTIBIOTIC DRUG.—

2 The term “essential generic antibiotic drug” means
3 an antibacterial or antifungal drug approved by the
4 Food and Drug Administration under section 505(j)
5 of the Federal Food, Drug, and Cosmetic Act (21
6 U.S.C. 355(j)) that the Secretary determines to be
7 medically necessary to have available at all times in
8 an amount adequate to serve patient needs, includ-
9 ing beta-lactams (including penicillin and
10 cephalosporin derivatives) and non-beta lactams (in-
11 cluding tetracycline and aminoglycoside derivatives).

12 (3) KEY STARTING MATERIAL.—The term “key
13 starting material” means any component of a drug
14 that the Secretary determines to be critical to the
15 safety and effectiveness of the drug.

16 (4) SECRETARY.—The term “Secretary” means
17 the Secretary of Health and Human Services.

18 (5) UNITED STATES.—The term “United
19 States” means the 50 States, the District of Colum-
20 bia, territories, and Tribal lands.

21 (d) FUNDING.—For purposes of carrying out this
22 section, there is appropriated, out of amounts in the
23 Treasury not otherwise appropriated, \$500,000,000 for
24 fiscal year 2021, to remain available through September
25 30, 2023.

1 **SEC. 3. STUDY AND REPORT.**

2 (a) IN GENERAL.—The Secretary of Health and
3 Human Services (referred to in this section as the “Sec-
4 retary”) shall enter into a contract with an entity under
5 which such entity carries out a study on the manufacture
6 of essential generic antibiotic drugs and issues a report
7 that includes—

8 (1) recommendations about which antibiotics
9 the Secretary should prioritize for purposes of the
10 program under section 2, based on factors that in-
11 clude necessity of use, vulnerability to foreign supply
12 chain disruptions, and availability of alternatives;
13 and

14 (2) the expected effect of increased domestic
15 manufacturing of drugs on drug costs to consumers.

16 (b) AUTHORIZATION.—To carry out this section,
17 there is authorized to be appropriated \$2,000,000 for fis-
18 cal year 2021, to remain available until September 30,
19 2022.

○